

EXHIBIT “A”

Mr. Ernie Molina
Warner-Jenkinson Company of California
P.O. Box 16797
Irvine, California 92713

Dear Mr. Molina:

This is in reply to your letter of January 17, 1980 concerning the labeling of vanilla flavoring with other natural flavors.

A flavoring composed of 50% vanilla extract and 50% natural flavors not derived from vanilla beans intended for retail sale may be identified as "vanilla flavor with other natural flavors". However, because "vanilla extract" and "vanilla" flavoring are standardized foods and these products are expensive we believe in order to distinguish this product from other similar products the general principles of 21 CFR FR 102.5 should apply. Thus, the name should be accompanied by "contains 50% vanilla extract and 50% non-vanilla flavors".

Since this product is to be sold at retail it must comply with the applicable labeling requirements of 21 CFR 101. These provisions would require at a minimum that the label for the food bear: (1) an identity statement; (2) an accurate net contents declaration; (3) a listing of each ingredient in the food by its common or usual name in descending order of predominance by weight; and (4) the name and address of the manufacturer, packer or distributor.

If we can be of further assistance, please let us know.

Sincerely yours,

Taylor M. Quinn
Associate Director
for Compliance
Bureau of Foods

EXHIBIT “B”



New Jersey Agricultural
Experiment Station

Mass Spectrometry Facility
Food Innovation Center North
Rutgers, The State University of NJ
63 Dudley Road
New Brunswick, NJ 08901-8520

Thomas G. Hartman, Ph.D.
Laboratory Director
hartmantg@aol.com
Phone: 848-932-5543
Fax: 732-932-6776

January 31, 2020

Spencer Sheehan, Esq.
Sheehan & Associates, P.C.
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Suite 311
Great Neck, NY 11021

spencer@spencersheehan.com

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Mass Spectrometry Laboratory Analysis Report #7608

Flavor Analysis of Westsoy Organic Unsweetened Vanilla Soymilk

Dear Mr. Sheehan:

This is the report pertaining to the above-captioned samples that you submitted for flavor analysis.

I Sample Log

The following samples were received for analysis:

1. Westsoy Organic Unsweetened Vanilla Soymilk
Production Code: 10219254714;44 1229629

II Analysis Request

The analysis request was to extract and analyze the flavors from the product.

III Analysis Methodology

The product (10 g) was transferred to a borosilicate glass test tube sealed with Teflon-lined, screw cap closure, matrix-spiked with 10 µg of naphthalene-*d*₈ internal standard (1.0 ppm w/v) and mixed thoroughly using a lab vortexor. The sample was then divided into 4 equal portions, transferred to glass vials and extracted with equal volumes (1:1) of methylene chloride. The layers were allowed to separate and then the methylene chloride extracts isolated and pooled together. The pooled extracts were centrifuged 30 minutes at 2500 rpm to clarify (separate any water or emulsion) then dried with anhydrous sodium sulfate. The dried extract was concentrated under a gentle stream of nitrogen to a final volume of approximately 0.5 mL then transferred to a Purge & Trap apparatus (Scientific Instrument Services, Solid Sample P&T system) and subjected to Purge & Trap-Thermal Desorption-GC-MS analysis as follows:

Purge & Trap-Thermal Desorption-GC-MS

Concentrated methylene chloride extract prepared as described above was evaporated to dryness in a stream of nitrogen gas inside the glass tubing of the purge & trap apparatus (SIS Solid Sample Purge & Trap Oven). Immediately upon reaching dryness the sample was subjected to P&T analysis by purging with nitrogen at 50 ml per minute for 30 minutes at 150°C. The exhaust of the P&T apparatus was fitted with a Tenax-TA adsorbent trap. The traps were then connected to the Short Path Thermal Desorption system and thermally desorbed directly into the GC-MS system for final analysis (SIS Model TD-4 Short Path Thermal Desorber). The thermal desorption conditions were 250°C for 5 minutes. A method blank was prepared and analyzed prior to the vanilla ice cream sample. Compounds detected in the method blank were disregarded in the data treatment of the test sample.

GC-MS Analysis Methodology

Analyses of Tenax traps prepared as described above were conducted using a Scientific Instrument Services (SIS) model TD4 Short Path Thermal Desorber interfaced to the Varian 3400 GC directly coupled to a Finnigan TSQ-7000 triple stage quadrupole tandem mass spectrometer equipped with an Xcaliber data system. Thermal desorption conditions were 250°C for 5 minutes using sub-

ambient, cryogenic GC column temperature programming. The GC was equipped with a 60 meter x 0.32 mm i.d. Guardian-ZB-5MS capillary column with a 1.0 μm film thickness (Phenomenex). The mass spectrometer was operated in electron ionization mode (70 eV) scanning masses 35-350 once each second.

Materials

Naphthalene- d_8 used as internal standard for the study was purchased from Sigma-Aldrich Chemical Co, St. Louis MO. Methylene chloride was purchased from Thermo Fisher Scientific. All thermal desorption supplies were purchased from Scientific Instrument Services, Inc., Ringoes, NJ.

IV Results

The GC-MS analysis data for the vanilla soymilk product is summarized in Table 1. The GC-MS chromatogram corresponding to the Table is presented in Figure 1. From left to right, the Table lists the MS scan number (from centroid of peak), peak area integration, peak identification and then concentration data expressed in parts per million (ppm w/v). The data is semi-quantitative and based on peak area ratio to the matrix-spiked internal standard (naphthalene- d_8) assuming a detector response factor of 1.0 with no correction for extraction efficiency.

If you have any questions or if I can be of further assistance to you then please don't hesitate to contact me.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Thomas G. Hartman", with a stylized flourish at the end.

Thomas G. Hartman, Ph.D.
Mass Spectrometry Lab Director
& Research Professor

Attachments

- ▶ Table 1, Analysis Results Summary
- ▶ Figure 1, GC-MS Chromatogram
- ▶ Analysis Data Forms
- ▶ Photo of Test Sample

Table 1

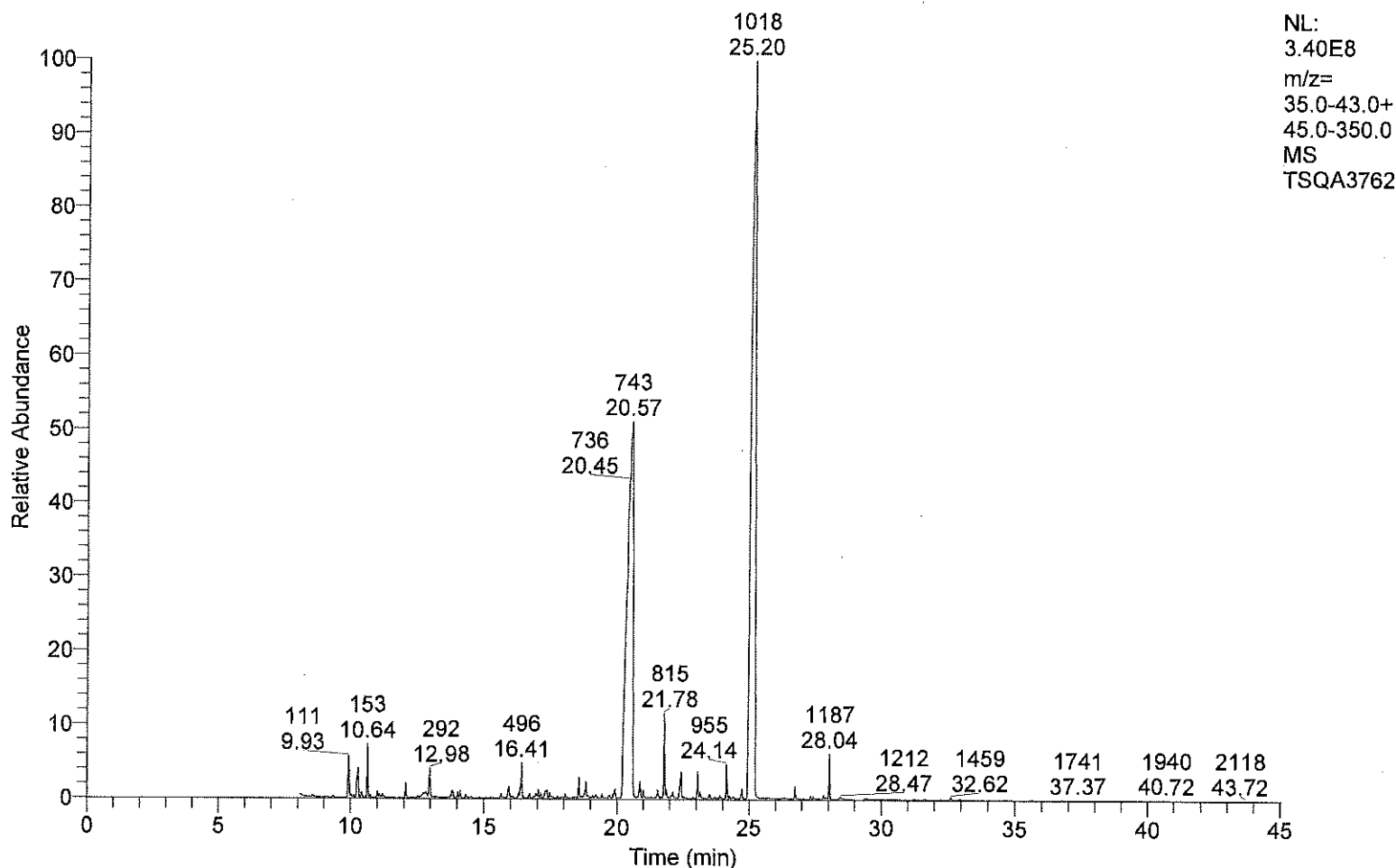
Sheehan & Associates, P.C., Project #7608
 Westsoy Organic Unsweetened Vanilla Soymilk
 Production Code: 10219254714:44 1229629

Methylene Chloride Extract of with 1 ppm Matrix-Spiked Int. Std. by P&T-TD-GC-MS

Data File = TSQA3762

MS Scan #	Area Integration	Peak Assignment	Conc. PPM w/w
132	1837527	diacetyl	1.18
186	110971	acetol	0.07
238	212546	acetoin	0.14
284	455852	1,2-propylene glycol (PG)	0.29
339	17449	hexanal	0.01
381	27961	methyl pyrazine	0.02
428	20701	hexyl alcohol	0.01
490	98469	gamma-butyrolactone	0.06
553	355555	hexanoic acid	0.23
559	124675	benzaldehyde	0.08
576	25500	2-pentylfuran	0.02
623	415090	cyclotene	0.27
639	362492	N-methylpyrrolidinone (NMP)	0.23
655	52342	gamma-hexalactone	0.03
661	123598	heptanoic acid	0.08
676	91395	2-acetylpyrrole	0.06
693	93935	guaiacol	0.06
700	62741	nonanal	0.04
705	296423	3-hydroxy-4,5(R)-dimethyl-2(5H)-furanone	0.19
743	45519020	maltol	29.23
761	482597	octanoic acid	0.31
769	138399	benzoic acid	0.09
800	209270	decanal	0.13
815	1557448	naphthalene-d8 (internal standard)	1.00
820	163504	2,3-dihydrobenzofuran	0.10
853	872541	nonanoic acid	0.56
890	451734	cinnamic aldehyde	0.29
941	81667	decanoic acid	0.05
955	699778	gamma-nonolactone	0.45
1018	60098160	vanillin	38.59
1110	280100	lauric acid	0.18
1187	765501	triethyl citrate	0.49
1212	141266	syringaldehyde	0.09
1269	83629	myristic acid	0.05
1459	84413	palmitic acid	0.05
Total			73.75

RT: 0.00 - 45.02



TSQA3762

Type: Unknown ID: 1 Row: 1

Sample Name: Westsoy Organic Unsweetened Vanilla Soymilk (Production Code: 10219254714:44 1229629), DCM Extract, 150C/30min, matrix spiked with w/w 1.0ppm Int. Std. by P&T-TD-GC-MS

Study: Sheehan & Associates, P.C., LLN7608

Laboratory: Mass Spectrometry - Dr. Tom Hartman

Company:

Phone:

Instrument Method: C:\Xcalibur\methods\voc45solventdelay8min.meth

Processing Method:

Vial: 1

Injection Volume (µl): 10.00

Sample Weight: 0.00

Sample Volume (µl): 0.00

ISTD Amount: 0.00

Dil Factor: 1.00

WESTBRAE  NATURAL[®]

WESTSOY[®]

Organic
Unsweetened
Vanilla
SOYMILK



See back panel for information about
the relationship between saturated fat,
cholesterol and heart disease.*

9g PROTEIN



32 FL OZ (1QT) 946 mL

Nutrition Facts

Serving Size 1 cup, 8 fl oz (240mL)

Servings Per Container 4

Amount per serving

Calories 100 **Calories from Fat** 45

% Daily Value*

Total Fat 5g **8%**

Saturated Fat 1g **5%**

Trans Fat 0g

Polyunsaturated Fat 3g

Monounsaturated Fat 1g

Cholesterol 0mg **0%**

Sodium 30mg **1%**

Potassium 390mg **11%**

Total Carbohydrate 4g **1%**

Dietary Fiber 1g **6%**

Sugars 3g

Protein 9g **18%**

Vitamin A 0% • Vitamin C 0%

Calcium 0% • Iron 8%

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	less than	65g	80g
Sat Fat	less than	20g	25g
Cholesterol	less than	300mg	300mg
Sodium	less than	2,400mg	2,400mg
Potassium		3,500mg	3,500mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g
Protein		50g	65g

INGREDIENTS: ORGANIC SOYMILK (FILTERED WATER, WHOLE ORGANIC SOYBEANS), NATURAL VANILLA FLAVOR WITH OTHER NATURAL FLAVORS.
CONTAINS: SOY

**MANUFACTURED FOR
DISTRIBUTION BY:**
THE HAIN CELESTIAL GROUP, INC.
LAKE SUCCESS, NY 11042 USA



**CERTIFIED ORGANIC
BY QUALITY ASSURANCE
INTERNATIONAL (QAI)**





APR 19 2005

Mr. Richard J. Brownell, Jr.
Vice President
Vanilla Products
Virginia Dare
882 Third Avenue
Brooklyn, New York 11232

Dear Mr. Brownell:

This is in response to your letter of February 10, 2005, to the Food and Drug Administration (FDA) regarding our October 8, 2004, letter to Rhodia, Inc. on the labeling of a vanillin product derived by fermentation. You requested clarification on our response to Rhodia, Inc. because you believe that it may be misinterpreted. In addition, you requested further clarification on whether a vanillin product derived by a natural process may be used to make natural vanilla flavors.

FDA's policy on the use of the term "natural" is that "natural" means that nothing artificial (including artificial flavors) or synthetic (including all color additives regardless of source) has been included in or has been added to a food that would not normally be expected to be in the food. Additionally, we do not restrict the use of the term "natural" except on products that contain added color, synthetic substances and flavors as defined in Title 21 of the Code of Federal Regulations (CFR), section 101.22.

As you know, on April 5, 2004, Rhodia, Inc. wrote to us requesting a letter confirming that vanillin derived from a natural source such as ferulic acid via a natural process such as fermentation can be labeled "natural vanillin" or "vanillin derived naturally by fermentation." In our October 8, 2004, response to Rhodia, Inc. we stated that the common or usual name of the product Rhodia, Inc. described in its letter is "vanillin." Further, we stated that if the product is manufactured by a natural process, we would not object to the use of a statement such as "vanillin derived naturally through fermentation" elsewhere on the product label because such statement indicates how the product was processed. However, the product Rhodia, Inc. described would not qualify as "natural vanillin." Thus, although we would not object to a statement on the label indicating that vanillin is derived naturally through a fermentation process, we point out that such a statement should not imply that the vanillin is a natural flavor or that a finished food containing it is natural.

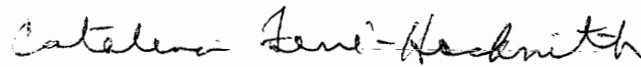
In your letter, you requested further clarification on whether a vanillin product derived by a natural process may be used to make natural vanilla flavors. The standards of identity for vanilla extract

Page 2 – Mr. Richard J. Brownell, Jr.

(21 CFR 169.175) and vanilla flavoring (21 CFR 169.177) do not provide for the use of vanillin. Therefore, vanillin may not be used to make natural vanilla flavors in such standardized foods.

If we may be of further assistance, please let us know.

Sincerely yours,

A handwritten signature in black ink, reading "Catalina Ferré-Hockensmith". The signature is written in a cursive style with a large, stylized 'C' and 'F'.

Catalina Ferré-Hockensmith
Consumer Safety Officer
Division of Food Labeling
and Standards
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

EXHIBIT “C”



AUG 05 2008

Richard J. Brownell Jr.
Vice President Vanilla Products
Virginia Dare Extracts, Inc.
882 Third Avenue
Brooklyn, New York 11232

Dear Mr. Brownell:

This is in response to your letter to the Food and Drug Administration (FDA) dated March 16, 2007, on the labeling of finished foods or beverages where vanilla is the characterizing flavor and the label refers to natural vanilla, vanilla flavor or some other similar description. We regret the delay in responding to your inquiry, and hope the following information is still helpful to you.

You specifically asked when a food or beverage product is marketed (labeled) as (natural) vanilla, does the characterizing (vanilla) flavor have to be derived from vanilla beans and conform to the vanilla standard of identity. According to our regulation in Title 21 of the Code of Federal Regulations (CFR), section 101.22(i)(1), if a food contains no artificial flavor that simulates, resembles or reinforces the characterizing flavor, the name of the food on the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., "vanilla." For example, the common or usual name of an ice cream product that does not contain artificial flavors would be "vanilla ice cream," and it should be made from vanilla beans. On the other hand, if a product such as ice cream does not contain enough of the characterizing ingredient, vanilla beans, to characterize the food or it does not contain such ingredient, and contains vanilla flavor, the product must be labeled "natural vanilla flavored ice cream" or "vanilla flavored ice cream." However, the flavors used to make such product must be derived from vanilla beans such as vanilla extract or vanilla flavor that are subject to standards of identity. Products made from vanillin should not be named "vanilla ____," e.g., "vanilla ice cream," or "vanilla flavored ____," e.g., "vanilla flavored ice cream" because these products are not made from vanilla beans or vanilla flavors made from vanilla beans. Furthermore, if a food contains any artificial flavor which resembles or reinforces the characterizing flavor, the name of the food on the label should be accompanied by the common or usual name of the characterizing flavor and the word(s) "artificial" or "artificially flavored", e.g., "artificial vanilla," "artificially flavored vanilla" or "vanilla artificially flavored."

Page 2- Mr. Richard J. Brownell Jr.

In our April 19, 2005, letter to you on the labeling of a Rhodia, Inc. vanillin product derived from a natural source such as ferulic acid via a natural process such as fermentation, we stated that this vanillin product "would not qualify as natural vanillin." In our April 19, 2005, letter we also stated that although we would not object to a statement on the label indicating that vanillin is derived naturally through a fermentation process, such a statement should not imply that the vanillin is a natural flavor or that a finished food containing vanillin is natural. However, upon further consideration on this issue, we realize that our views about vanillin expressed in the April 19, 2005, letter were based on the food standards regulations under sections 169.180, 169.181, and 169.182 in 21 CFR.

These regulations pertain to standardized vanilla extract ingredients that contain added vanillin and require the designation "contains vanillin, an artificial flavor (or flavoring)". However, it should be noted that these regulations pre-date the fermentation process that Rhodia uses to produce vanillin. Also, 21 CFR 101.22(a)(1) provides that fermentation products are not considered to be artificial flavors. Thus, the new Rhodia process produces a natural flavor and consequently, the ingredient label of a finished food containing the vanillin product made by Rhodia can bear the term "vanillin," "natural flavor" or "contains natural flavor" but the term "natural flavor" must not be used in such a way to imply that it is a "natural vanilla flavor" because it is not derived from vanilla beans. Furthermore, the term "natural" is not a part of the common or usual name of Rhodia's product when sold as the finished food. The common or usual name of Rhodia's product is "vanillin," regardless of the type of method used to produce it. Therefore, the statement of identity of the product sold as the finished food is "vanillin."

If we may be of further assistance, please let us know.

Sincerely yours,



Catalina Ferré-Hockensmith
Food Labeling and Standards Staff
Office of Nutrition, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

EXHIBIT “D”



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

October 10, 2008

Ms. Agneta Weisz
Comax Flavors
130 Baylis Road
Melville, NY 11747

Dear Ms. Weisz:

This is in response to your letter, dated November 15, 2007, requesting the Food and Drug Administration's (FDA) opinion as to whether vanillin produced by a fermentation process developed by Comax Flavors (Comax) would be considered a natural flavoring substance in accordance with section 101.22 (a)(3) in Title 21 of the Code of Federal Regulations (21 CFR). Along with your letter you submitted a description of the manufacturing process and information on product analysis and specifications. In a letter, dated December 11, 2007, you submitted additional information on the chemical analysis of your product.

Based on the information you submitted, we have determined that Comax's fermentation process for vanillin production can be considered to be a natural process. As such, Comax's vanillin product can be categorized as a natural flavor in accordance with section 101.22 (a)(3). However, with respect to labeling, the common or usual name of the product you describe is "vanillin," regardless of the type of method used to produce it. Therefore, the product should be labeled as "vanillin." FDA would expect vanillin to be produced by either Comax or synthetically to meet the specifications listed in the Food Chemicals Codex (FCC) in order to be acceptable for food use. If the substance happens to be manufactured through a natural process, as in the case of Comax's fermentation process, this can be indicated by an additional labeling statement referring to the manufacturing process (e.g., "vanillin derived naturally through fermentation" or "natural" somewhere else on the label).

Moreover, we point out that when vanillin manufactured through a natural process such as Comax's vanillin is used as an ingredient in another finished food, it should be listed in the ingredient list as "vanillin" or "natural flavor" but it should not be done in a way to imply that it is a "natural vanilla flavor" because it is not derived from vanilla beans.

Please contact us again if you have further questions regarding this matter.

Sincerely,

A handwritten signature in black ink, reading "Negash Belay", is written over the word "Sincerely,".

Negash Belay, Ph.D.

Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition